

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PACIRA PHARMACEUTICALS, INC., and
PACIRA BIOSCIENCES, INC.,

Plaintiffs,

v.

EVENUS PHARMACEUTICALS
LABORATORIES INC., JIANGSU
HENGRIU PHARMACEUTICALS CO.,
LTD., and FRESENIUS KABI USA LLC,

Defendants.

Civil Action No. 2:21-cv-19829-MCA-
JRA (consolidated with Civil Action No.
2:22-cv-00718-MCA-JRA)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiffs Pacira Pharmaceuticals, Inc. and Pacira Biosciences, Inc. (collectively, “Pacira” or “Plaintiffs”) and Defendants eVenus Pharmaceuticals Laboratories, Inc. (“eVenus”), Jiangsu Hengrui Pharmaceuticals Co., Ltd., and Fresenius Kabi USA, LLC, (collectively, “Defendants”) hereby submit their Joint Claim Construction and Prehearing Statement in accordance with Local Patent Rule 4.3 and the Scheduling Order (D.I. 86) (as modified by the Court’s Oct. 20, 2022 Order, D.I. 96).

I. BACKGROUND

This case arises out of eVenus’s filing of ANDA No. 214348 with the U.S. Food and Drug Administration (“FDA”), which seeks approval to market a generic version of Plaintiffs’ EXPAREL® product. Plaintiffs assert, among other things, that eVenus’s submission of ANDA No. 214348 to the FDA constitutes infringement of U.S. Patent Nos. 11,033,495 (the ““495 Patent”) and 11,179,336 (the ““336 Patent”) (collectively, the “patents-in-suit”). Defendants assert

that all claims of the patents-in-suit are not infringed or are invalid, including as anticipated by the prior art EXPAREL® product, which has been on the U.S. market since 2012.

Pursuant to Local Patent Rules 4.2(a)-(b), on September 30, 2022, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their proposed Preliminary Constructions. Pursuant to Local Patent Rule 4.2(c), on October 12, 2022, the parties identified intrinsic and extrinsic evidence that each party intends to rely upon to oppose any other party's proposed construction. Pursuant to Local Patent Rule 4.2(d), on October 19, 2022, counsel for the parties met and conferred for the purposes of narrowing the issues and preparing the Joint Claim Construction and Prehearing Statement.

II. CONSTRUCTION OF PATENT TERMS

A. Local Patent Rule 4.3(a): Agreed Upon Claim Constructions

The parties agree to the construction of the following term:

Term	Patent, Claims	Construction
“comprising phosphoric acid”	’495 Patent, claims 1-22	“including, but not limited to, phosphoric acid”

The parties additionally agree that the following terms from the claims of the ’495 Patent should be construed as product-by-process limitations. The parties do not concede, or propose that the Court address at this time, whether the classification of these terms as product-by-process limitations has any substantive bearing on what Plaintiffs need to prove to establish infringement or what Defendants need to prove to establish invalidity.

Term	Patent, Claims
element 1(a); element 1(b); element 1(c); element 1(d); element 1(f); and “wherein all steps are carried out under aseptic conditions”	’495 Patent, claims 1-22

Term	Patent, Claims
“wherein the mixing in step (a) is performed using a first mixer at a high shear speed”	'495 Patent, claim 9
“wherein the high sheer speed is from about 1100 rpm to about 1200 rpm”	'495 Patent, claim 10
“wherein the high sheer speed is about 1150 rpm”	'495 Patent, claim 11
“wherein the mixing time in step (a) is about 65 to 75 minutes”	'495 Patent, claim 12
“wherein the mixing in step (b) is performed using a second mixer at a low shear speed”	'495 Patent, claim 13
“wherein the low shear speed is from about 450 rpm to about 510 rpm”	'495 Patent, claim 14
“wherein the low shear speed is about 495 rpm”	'495 Patent, claim 15

B. Local Patent Rule 4.3(a): Disputed Claim Terms

Attached hereto as Exhibit A is a claim chart identifying the claim terms in dispute, the parties' proposed constructions, and the evidence (both intrinsic and extrinsic) that each party intends to rely on in support of its proposed construction or to oppose the other party's proposed construction. Included in the below table is a summary of the disputed claim terms and their corresponding patent and claim numbers:

Term	Patent(s), Claim(s)
Defendants propose the following term from the preambles of claim 1 of the '495 Patent and claim 1 of the '336 Patent. Plaintiffs agree that the Court should construe it with respect to the '336 Patent but dispute that it is appropriate to separate the term from the full preamble of the '495 Patent.	'495 Patent, claims 1-22 '336 Patent, claims 1-20
“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)”	

Term	Patent(s), Claim(s)
Plaintiffs propose to construe the full preamble of claim 1 of the '495 Patent. Defendants dispute that it is appropriate to construe the full preamble as a single term and propose for construction only “commercial scale,” in addition to the term identified above, both of which appear in the preamble of claim 1 of '495 Patent. “A composition of bupivacaine encapsulated multivesicular liposomes (MVLs) prepared by a commercial scale process” (proposed by Plaintiffs) “commercial scale” (proposed by Defendants)	'495 Patent, claims 1-22
“a high shear speed” / “a low shear speed”	'495 Patent, claims 9-15
“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is about 5.5” / “wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5”	'495 Patent, claim 19 / '336 Patent, claims 1-20
Defendants contend that the term below should be construed as a product-by-process claim limitation as part of claim construction: “prepared by a commercial scale process”	'495 Patent, claims 1-22

C. Local Patent R. 4.3(c): Claim Terms Whose Construction Will Be Most Significant

Plaintiffs' Position:

Plaintiffs submit that there are no terms whose construction will be “most significant to the resolution of the case,” “case or claim dispositive,” or “substantively conducive to promoting settlement.” The “composition[s]” claimed in the '495 and '336 Patents, respectively, are new compositions with different properties than the EXPAREL® product Pacira manufactured using its prior process. To the extent Defendants’ have raised arguments that the asserted claims are invalid based on the alleged prior art EXPAREL® product, these arguments do not turn on the construction of any particular claim term.

Defendants' Position:

Defendants submit that construction of the terms “[a] composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” (contained in every claim of the patents-at-issue) and “[commercial scale]” (contained in every claim of the ’495 Patent) will be most significant to the resolution of the case. Defendants assert that the asserted claims are invalid as at least anticipated and/or obvious in view of the prior art EXPAREL® product, which has been commercially available in the United States since 2012. Defendants dispute Plaintiffs’ assertion that the “compositions” claimed in the ’495 and ’336 Patents are “new compositions with different properties.” In any case, there should be no reasonable dispute that, under Defendants’ proposed constructions, the prior art EXPAREL® product is “a composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” that was produced at “commercial scale.”

D. Local Patent Rule 4.3(d): Anticipated Length of Time Necessary for the Claim Construction Hearing

The parties anticipate that the Court will be able to conduct a hearing on the meaning of the disputed terms in three to four hours.

Pacira believes it would be beneficial to the Court to hold a technology tutorial and that the Court should allocate twenty minutes per side for a tutorial followed by three hours of argument, divided equally between the parties.

Defendants propose that the hearing should be limited to three hours total and that any technology tutorial offered by a party should count against that party’s argument time.

E. Local Patent Rule 4.3(e): Identification of Witnesses for the Claim Construction Hearing

The parties may rely on declarations by their respective experts setting forth opinions related to the disputed claim terms. The parties, however, do not anticipate a need for live testimony at the claim construction hearing.

Dated: October 21, 2022

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Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
<p>Defendants propose the following term from the preambles of claim 1 of the '495 Patent and claim 1 of the '336 Patent. Plaintiffs agree that the Court should construe it with respect to the '336 Patent but dispute that it is appropriate to separate the term from the full preamble of the '495 Patent.</p> <p>"A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)"</p> <p>'495 Patent, claims 1-22 '336 Patent, claims 1-20;</p>	<p><u>Plaintiffs' Proposed Construction</u></p> <p>(Plaintiffs propose to construe this term, which is the preamble of claim 1 of the '336 Patent. To the extent this language appears as a portion of the preamble of claim 1 of the '495 Patent, Plaintiffs dispute that it is appropriate to separate the term from the full preamble there. Plaintiffs have provided their construction and proposed construction for the preamble of claim 1 of the '495 Patent below.)</p> <p>The preamble of claim 1 of the '336 Patent is limiting and should be construed as:</p> <p>"An aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs) having a batch-to-batch consistency"</p> <p><u>Evidence</u></p> <p><u>Intrinsic evidence:</u></p> <p>'336 Patent generally, including but not limited to, 1:8-10, 1:39-43, 2:63-3:8, 3:48-61, 4:14-46, 4:53-5:4, 5:62-6:23, 13:30-63, 14:36-15:25, 16:9-64, 17:58-19:17, 20:17-20, 20:26-22:40, Tables 1A, 1B, 2A, 2B, Figures 3A-3C, claims 1-8.</p> <p>'336 Patent File History generally, including but not limited to, September 2, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; September 2, 2021 Amendment and Response to Non-Final Office; September 22, 2021 Notice of Allowance. PAC-EXPAREL00796398 – 796813.</p>	<p><u>Defendants' Proposed Construction</u></p> <p>"A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)" means "a multivesicular liposome composition encapsulating bupivacaine"</p> <p><u>Evidence</u></p> <p><u>Intrinsic evidence:</u></p> <p>U.S. Patent No. 11,179,336 ("the '336 Patent"): Claims 1-20; Abstract; Figures 3A, 3B, 3C; Examples 1-2 & Tables 1A-2B; 2:27-3:61; 4:14-30; 4:54-5:14; 5:51-6:23; 6:24-7:58; 13:29-16:30; 17:34-20:23.</p> <p>U.S. Patent No. 11,033,495 ("the '495 Patent"): Claims 1-22.</p> <p>File History of the '336 Patent: July 16, 2021 Office Action; Applicant-Initiated Interview Summary for August 3, 2021 Interview; Amendment and Response to July 16, 2021 Office Action; Sept. 2, 2021 Declaration of Kathleen Los; Notice of Allowability.</p> <p>File History of the '495 Patent: March 25, 2021 Non-Final Rejection; April 22, 2021 Amendment and Response to Non-Final Office Action; Decl. of Ms. Kathleen Los under 37 CFR 1.132; Notice of Allowability</p> <p>U.S. Patent No. 11,429,348: Claims 1-50.</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
	<p>'495 Patent File History generally, including but not limited to, April 21, 2021 Examiner Interview Summary, April 22, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; April 22, 2021 Amendment and Response to Non-Final Office Action; May 7, 2021 Notice of Allowance. PAC-EXPAREL00000459 – 2819.</p> <p>'495 Patent generally, including but not limited to, the corresponding disclosure of the '336 Patent citations set forth above.</p> <p><u>Extrinsic evidence:</u></p> <p>Plaintiffs may rely on testimony from an expert including, but not limited to, Alexander M. Klibanov, Ph.D., and/or opinions regarding how a person of ordinary skill in the art would have understood the meaning of the preamble language based on the disclosures in the patent specification, other intrinsic evidence, and extrinsic evidence, including regarding the limiting nature of the preamble language, and further to rebut any positions taken by Defendants.</p> <p>Plaintiffs may rely on any intrinsic or extrinsic evidence identified by Defendants, including the full versions of any partially referenced documents.</p> <p>Plaintiffs further incorporate by reference the intrinsic and extrinsic evidence cited above with respect to the preamble language of the '495 Patent to the extent such evidence is not otherwise identified herein.</p>	<p>Defendants may rely on any intrinsic evidence identified by Plaintiffs.</p> <p><u>Extrinsic evidence:</u></p> <p>Based on Plaintiffs' disclosure of their intent to use an expert, Defendants may rely on testimony from an expert including, but not limited to, Alpaslan Yaman, Ph.D., and/or opinions regarding how a person of ordinary skill in the art would have understood the preamble language (including the term "a composition of bupivacaine encapsulated multivesicular liposomes (MVLs)") based on the disclosures in the patent specifications, other intrinsic evidence, and extrinsic evidence, including regarding the nature and scale of the claimed composition, and further to rebut any positions taken by Plaintiffs.</p> <p>Defendants may rely on any extrinsic evidence identified by Plaintiffs.</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
<p>Plaintiffs propose to construe the full preamble of claim 1 of the '495 Patent. Defendants dispute that it is appropriate to construe the full preamble as a single term and instead propose for construction only “commercial scale,” in addition to the term identified above, both of which appear in the preamble of claim 1 of the '495 Patent.</p> <p>“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs) prepared by a commercial scale process” (proposed by Plaintiffs)</p> <p>“commercial scale” (proposed by Defendants)</p> <p>'495 Patent, claims 1-22</p>	<p>Plaintiffs' Proposed Construction</p> <p>(Plaintiffs propose to construe the preamble of claim 1 of the '495 Patent as a whole, which incorporates the shorter terms Defendants propose.)</p> <p>The preamble of claim 1 of the '495 Patent is limiting and should be construed as:</p> <p>“An aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs) having a batch volume greater than about 45 liters to about 250 liters prepared by a process”</p> <p>Evidence</p> <p><u>Intrinsic evidence:</u></p> <p>'495 Patent generally, including but not limited to, Abstract, 1:8-10, 1:15-17, 1:32-36, 3:1-55, 3:58-4:24, 4:28-40, 4:47-5:3, 5:56-13:23, 13:49-19:21, 20:13-16, 20:29-22:41, Tables 1A, 1B, 2A, 2B, Figures 1A, 1B, 2, 3A-3C, claims 1-8.</p> <p>'495 Patent File History generally, including but not limited to, April 21, 2021 Examiner Interview Summary, April 22, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; April 22, 2021 Amendment and Response to Non-Final Office Action; May 7, 2021 Notice of Allowance. PAC-EXPAREL00000459 – 2819.</p> <p>'336 Patent generally, including but not limited to, the corresponding disclosure of the '495 Patent citations set forth above.</p>	<p>Defendants' Proposed Construction</p> <p>“commercial scale” means “a scale of manufacturing for production of a commercial product”</p> <p>Evidence</p> <p><u>Intrinsic evidence:</u></p> <p>The '336 Patent: Abstract, Examples 1-2 & Tables 1A-2B; '336 patent at 1:10-4:46, 4:54-5:14, 5:51-6:23, 6:24-7:58, 12:48-14:35, 15:17-62, 16:31-64, 17:34-56, 17:57-20:23.</p> <p>U.S. Patent No. 9,585,838 (“838 patent”): Abstract; claims 1-43; 1:43-57; 3:26-30; 5:10-24; 13:1-14.</p> <p>File History of the '495 Patent: March 25, 2021 Non-Final Rejection; April 22, 2021 Amendment and Response to Non-Final Office Action; Decl. of Ms. Kathleen Los under 37 CFR 1.132; Notice of Allowability; U.S. 2014/0004173.</p> <p>File History of the '336 Patent: July 16, 2021 Office Action; Applicant-Initiated Interview Summary for August 3, 2021 Interview; Amendment and Response to July 16, 2021 Office Action; Sept. 2, 2021 Declaration of Kathleen Los; Notice of Allowability.</p> <p>File History of the '838 Patent:</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
	<p>'336 Patent File History generally, including but not limited to, September 2, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; September 2, 2021 Amendment and Response to Non-Final Office; September 22, 2021 Notice of Allowance. PAC-EXPAREL00796398 – 796813.</p> <p>U.S. Patent No. 9,585,838 (the “‘838 patent”) generally, including but not limited to, 3:27-58, 5:10-24, 7:15-23, 10:32-11:14, Examples 1-17, Tables 1-7, Figures 1-22 and related descriptions.</p> <p>'838 Patent File History, May 21, 2014 Submission with RCE. PAC-EXPAREL00796886 – 796903.</p> <p><u>Extrinsic evidence:</u></p> <p>Pacira Pharmaceuticals Q2 2017 Results - Earnings Call Transcript, April 2, 2017; Pacira Pharmaceuticals Q2 2018 Results - Earnings Call Transcript, August 2, 2018; Pacira Pharmaceuticals Q2 2019 Earnings Call Transcript, August 8, 2019; Process Facilities Group, March 2, 2016 WayBack Machine Capture. PAC-EXPAREL00796814 – 79879.</p> <p>U.S. Publication No. 2014/0004173. PAC-EXPAREL00796265 – 96299</p> <p>Plaintiffs may rely on knowledge of one or more percipient witnesses regarding information about Pacira’s 45-liter manufacturing process.</p> <p>Plaintiffs may rely on testimony from an expert including, but not limited to, Alexander M. Klibanov, Ph.D., and/or opinions regarding how</p>	<p>November 22, 2013 Office Action (eVenus-00037223-233); April 21, 2014 Schutt Declaration (eVenus-00037221-222).</p> <p>Defendants may rely on any intrinsic evidence identified by Plaintiffs.</p> <p><u>Extrinsic evidence:</u></p> <p>PAC-EXPAREL00351630-651; PAC-EXPAREL00671740-756; PAC-EXPAREL00681052-065; PAC-EXPAREL00681891-899; PAC-EXPAREL00682496-518; PAC-EXPAREL00685927-932; PAC-EXPAREL00685933-942; PAC-EXPAREL00790593-598</p> <p>FDA Feb. 2018 Draft Guidance on Bupivacaine (eVenus-00037249-251)</p> <p>Based on Plaintiffs’ disclosure of their intent to use an expert, Defendants may rely on testimony from an expert including, but not limited to, Alpaslan Yaman, Ph.D., and/or opinions regarding how a person of ordinary skill in the art would have understood the preamble language (including the term “commercial scale”) based on the disclosures in the patent specifications, other intrinsic evidence, and extrinsic evidence, including regarding the nature and scale of the claimed composition, and further to rebut any positions taken by Plaintiffs.</p> <p>Defendants may rely on any extrinsic evidence identified by Plaintiffs.</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
	<p>a person of ordinary skill in the art would have understood the meaning of the preamble language based on the disclosures in the patent specification, other intrinsic evidence, and extrinsic evidence, and including regarding the nature and scale of the claimed composition, and further to rebut any positions taken by Defendants.</p> <p>Plaintiffs may rely on any intrinsic or extrinsic evidence identified by Defendants, including the full versions of any partially referenced documents.</p> <p>Plaintiffs further incorporate by reference the intrinsic and extrinsic evidence cited below with respect to the preamble language of the '336 Patent to the extent such evidence is not otherwise identified herein.</p>	
<p>“a high shear speed” / “a low shear speed”</p> <p>'495 Patent, claims 9-13</p>	<p><u>Plaintiffs' Proposed Construction</u></p> <p>Plain and ordinary meaning:</p> <p>“a high shear speed” / “a low shear speed”</p> <p><u>Evidence</u></p> <p><u>Intrinsic evidence:</u></p> <p>'495 Patent generally, including but not limited to, 5:56-6:17, 7:53-8:34, 9:50-64, 16:57-17:25, claims 9, 10, 11, 13, 14, 15.</p> <p>'336 Patent generally, including but not limited to, the corresponding disclosure of the '495 Patent citations set forth above.</p> <p><u>Extrinsic evidence:</u></p>	<p><u>Defendants' Proposed Construction</u></p> <p>“a single high shear speed” / “a single low shear speed”</p> <p><u>Evidence</u></p> <p><u>Intrinsic evidence:</u></p> <p>The '336 Patent: 7:59-8:39, 9:55-10:2, 16:65-17:33.</p> <p>The '495 Patent: Claims 9-16.</p> <p>File History of the '495 Patent: March 25, 2021 Non-Final Rejection; April 22, 2021 Amendment and Response to Non-Final Office Action; Decl.</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
	<p>Plaintiffs may rely on testimony from an expert including, but not limited to, Alexander M. Klibanov, Ph.D., and/or opinions regarding how a person of ordinary skill in the art would have understood the meaning of the terms “a high shear speed” and “a low shear speed” based on the disclosures in the patent specifications, other intrinsic evidence, and extrinsic evidence, including regarding the nature of the shear speeds set forth in the patents, and further to rebut any positions taken by Defendants.</p> <p>Plaintiffs may rely on any intrinsic or extrinsic evidence identified by Defendants, including the full versions of any partially referenced documents.</p>	<p>of Ms. Kathleen Los under 37 CFR 1.132; Notice of Allowability.</p> <p>Defendants may rely on any intrinsic evidence identified by Plaintiffs.</p> <p><u>Extrinsic evidence:</u></p> <p>Based on Plaintiffs’ disclosure of their intent to use an expert, Defendants may rely on testimony from an expert including, but not limited to, Alpaslan Yaman, Ph.D., and/or opinions regarding how a person of ordinary skill in the art would have understood the meaning of the terms “a high shear speed” and “a low shear speed” based on the disclosures in the patent specifications, other intrinsic evidence, and extrinsic evidence, including regarding the nature of the shear speeds set forth in the patents, and further to rebut any positions taken by Plaintiffs.</p> <p>Defendants may rely on any extrinsic evidence identified by Plaintiffs.</p>
<p>“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is about 5.5”</p> <p>’495 Patent, claim 19</p> <p>“wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5”</p>	<p><u>Plaintiffs' Proposed Construction</u></p> <p>Plain and ordinary meaning:</p> <p>“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is approximately 5.5”</p> <p>“wherein the plurality of internal aqueous chambers of the MVLs has a pH of approximately 5.5”</p>	<p><u>Defendants' Proposed Construction</u></p> <p>“wherein the pH of the internal aqueous chambers of the bupivacaine encapsulated MVLs in the composition is greater than or equal to 5.45 and less than 5.55”</p> <p>“wherein the plurality of internal aqueous chambers of the MVLs has a pH is greater than or equal to 5.45 and less than 5.55”</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
'336 Patent, claims 1-20	<p>Evidence</p> <p><u>Intrinsic evidence:</u></p> <p>'495 Patent generally, including but not limited to, 2:64-67, 3:36-40, 3:50-4:4, 4:35-65, 5:56-6:17, 12:42-13:23, 13:49-59, 14:25-15:18, 15:53-59, 16:1-19:21, 20:23-22:41, Tables 1A, 1B, 2A, 2B, Figures 3A-3C, claims 1-19.</p> <p>'336 Patent generally, including but not limited to, the corresponding disclosure of the '495 Patent citations set forth above and claims 1-17.</p> <p>'495 Patent File History generally, including but not limited to, April 21, 2021 Examiner Interview Summary, April 22, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; April 22, 2021 Amendment and Response to Non-Final Office Action; May 7, 2021 Notice of Allowance. PAC-EXPAREL00000459 – 2819.</p> <p>'336 Patent File History generally, including but not limited to, September 2, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; September 2, 2021 Amendment and Response to Non-Final Office; September 22, 2021 Notice of Allowance. PAC-EXPAREL00796398 – 796813.</p> <p><u>Extrinsic evidence:</u></p> <p>NEW OXFORD AMERICAN DICTIONARY 5 (3rd ed. 2010). PAC-EXPAREL00796880 – 796882.</p> <p>RANDOM HOUSE WEBSTER'S UNABRIDGED DICTIONARY 6 (2d ed. 2001). PAC-EXPAREL00796883 – 796885.</p>	<p>Evidence</p> <p><u>Intrinsic evidence:</u></p> <p>The '336 Patent: Fig. 3, Examples 1-2 & Tables 1A-2B; 1:10-4:46; 4:54-5:20; 5:51-6:23; 8:40-59; 12:48-15:2; 15:26-16:64; 18:58-19:9.</p> <p>File History of the '336 Patent: July 16, 2021 Office Action; Applicant-Initiated Interview Summary for August 3, 2021 Interview; Amendment and Response to July 16, 2021 Office Action; Sept. 2, 2021 Declaration of Kathleen Los; Notice of Allowability.</p> <p>File History of the '495 Patent: April 21, 2021 Examiner Interview Summary, April 22, 2021 Declaration of Ms. Kathleen Los Under CFR 1.132; April 22, 2021 Amendment and Response to Non-Final Office Action; May 7, 2021 Notice of Allowance.</p> <p>File History of U.S. Patent No. 11,357,727: January 19, 2022 Response to Office Action; Dec. 24, 2021 Office Action.</p> <p>Defendants may rely on any intrinsic evidence identified by Plaintiffs.</p> <p><u>Extrinsic evidence:</u></p> <p>Based on Plaintiffs' disclosure of their intent to use an expert, Defendants may rely on testimony from an expert including, but not limited to, Alpaslan Yaman, Ph.D., and/or opinions regarding how a person of ordinary skill in the art</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
	<p>Plaintiffs may rely on testimony from an expert including, but not limited to, Alexander M. Klibanov, Ph.D., and/or opinions regarding how a person of ordinary skill in the art would have understood the meaning of the pH terms based on the disclosures in the patent specifications, other intrinsic evidence, and extrinsic evidence, including regarding the nature of pH measurements, and further to rebut any positions taken by Defendants.</p> <p>Plaintiffs may rely on any intrinsic or extrinsic evidence identified by Defendants, including the full versions of any partially referenced documents.</p>	<p>would have understood the meaning of the pH terms based on the disclosures in the patent specifications, other intrinsic evidence, and extrinsic evidence, including regarding the nature of pH measurements, and further to rebut any positions taken by Plaintiffs.</p> <p>Defendants may rely on any extrinsic evidence identified by Plaintiffs.</p>
<p>“prepared by a commercial scale process”</p> <p>(‘495 Patent, claims 1-22)</p>	<p>Plaintiffs assert that this portion of the preamble of claim 1 of the ‘495 patent should be considered as part of the full preamble and is limiting. Plaintiffs’ supporting evidence is set out above in connection with the full preamble term. To the extent the term “prepared by a commercial scale process” informs the meaning of the full preamble and the claimed “composition,” Plaintiffs dispute that it is a product-by-process limitation.</p>	<p>Defendants contend that the identified term should be construed as a product-by-process claim limitation as part of claim construction. Defendants are not asking the Court to rule at this stage of the case as to whether the classification of this claim term as a product-by-process claim limitations affects what the parties need to prove on the merits with respect to infringement and invalidity.</p> <p><u>Evidence</u></p> <p><u>Intrinsic evidence:</u></p> <p>The ’336 patent: Fig. 3; ’336 patent, Abstract; ’336 patent at 1:10-4:46, 4:54-5:14, 5:51-6:23, 6:24-7:58, 9:24-10:49.</p> <p>File History of the ’495 Patent: March 25, 2021 Non-Final Rejection; April 21, 2021 Applicant-</p>

Claim Term/Phrase for Construction	Plaintiffs' Proposed Constructions and Evidence	Defendants' Proposed Constructions and Evidence
		<p>Initiated Interview Summary; April 22, 2021 Amendment and Response to Non-Final Office Action; Decl. of Ms. Kathleen Los under 37 CFR 1.132; Notice of Allowability.</p> <p>File History of U.S. Patent No. 11,278,494: April 7, 2021 Office Action; July 7, 2021 Response to April 7, 2021 Office Action.</p> <p>Defendants may rely on any intrinsic evidence identified by Plaintiffs.</p> <p><u>Extrinsic evidence:</u></p> <p>Pacira BioSciences Corporate Presentation dated November 2021, Page 9 (eVenus-00037022-044)</p> <p>Pacira BioSciences Corporate Presentation dated Sept. 2022 (eVenus-00037185-7205)</p> <p>August 3, 2021 Pacira Earning Call (eVenus-00037252-7300)</p> <p>Defendants may rely on any extrinsic evidence identified by Plaintiffs.</p>